

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

Date:

5/27/10

SUBJECT: Pyraclostrobin. Human Health Risk Assessment for the Decrease in Application

Volume and Increase in Soybean Forage and Hay Tolerances.

PC Code: 099100

Decision No.: 416999 **Petition Nos.:** 9F7569

Risk Assessment Type: N/A

TXR No.: N/A MRID No.: 47774701-02 **DP Barcode:** 378282

Registration No.: 7969-186, 7969-289
Regulatory Action: Section 3 Registration

Merchanp

Case No.: N/A

CAS No.: 175013-18-0 40 CFR: 180.582

Ver.Apr.08

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FROM:

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Alternative Risk Integration and Assessment (ARIA) Team

Risk Integration, Minor Use and Emergency Response Branch (RIMUERB)

Registration Division (RD; 7505P)

THROUGH: P. Deschamp, Branch Chief

Risk Assessment Branch III (RABII)

Health Effects Division (HED; 7509)

TO:

T. Kish/S. Hill, RM# 22

Fungicide Branch RD (7505P)

ARIA/RIMUERB of RD of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. RD of OPP has requested that ARIA evaluate hazard and exposure data and conduct dietary, occupational, residential and aggregate exposure assessments, as needed, to estimate the risk to human health that will result from proposed and currently registered uses of the active ingredient pyraclostrobin.

The overall risk assessment, dietary risk assessment, and residue chemistry assessment were provided by W. Cutchin.

Pyraclostrobin

Human Health Risk Assessment

DP#: 378282

This document will only address the differences in the human health risk assessment from the last assessment. The remainder of the original assessment remains unchanged (PP# 9F7528, DP Num.: 362855, W. Cutchin, 11/18/09).

Executive Summary

BASF requests the increase in tolerances for the combined residues of the fungicide pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1*H*- pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-*N*-[[[1-(4-chlorophenyl)pyrazol-3-yl]oxy]-o-tolyl] carbamate), expressed as parent compound, in/on the following commodities:

Soybean, forage	11.0 ppm
Soybean, hay	14.0 ppm

Concurrently, BASF wishes to amend the registration of Headline® Fungicide (EPA Reg. No. 7969-186) and Headline® SC Fungicide (EPA Reg. No. 7969-1289) to permit aerial application at spray volumes down to 1 gallon per acre (GPA). Both Headline®, an EC formulation, and Headline® SC, a soluble concentrate formulation, contain 23.6% ai (2.09 lb ai/gal) of pyraclostrobin. The proposed use is two applications at the maximum seasonal rate of 0.2 lb ai/A. The application may be made using ground or aerial equipment. The proposed preharvest intervals (PHI) range to the beginning of flowering stage (25%) at 21 days.

Dietary (Food & Drinking Water) Exposure Assessment

ARIA has determined that the residue chemistry database is adequate to support the proposed change in use pattern and increases in the soybean forage and hay tolerances. Soybean forage and hay are not human food items, and the increases in hay and forage tolerances do not require an increase in existing meat, milk, poultry and egg tolerances (PP# 9F7590, DP Num.: 371252, W. Cutchin, 5/26/10). Environmental Fate and Effects Division's (EFED) previous drinking water assessment was based on the existing registered use of aerial application on turf and ornamentals representing the highest application rate at 0.5 lbs ai/acre with 6 maximum seasonal applications at 14 day intervals. EFED believed that the aerial use of pyraclostrobin on turf and ornamentals would pose the upper-bound concentrations in surface and ground water since spray drift increases and application efficiency decreases in an aerial application technique (DP Num: 362852, R. Miller; 10/14/09). Therefore, the proposed use on soybeans will not result in a higher exposure to pyraclostrobin in drinking water. Since there is no increase in dietary (food + drinking water) exposure to pyraclostrobin, a reassessment of the last dietary risk analysis (PP# 9F7528, DP Num.: 369379, W. Cutchin, 10/30/09) is not required.

Residential Exposure

No new residential uses of pyraclostrobin are proposed in this petition. A product containing pyraclostrobin (i.e., Insignia[®]) is registered for application to residential turf grass and recreational sites and was included in the last human health risk assessment.

Pyraclostrobin

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Aggregate Risk

In accordance with the FQPA, ARIA must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. Since there are no changes in the expected exposures from the three major sources, there is no change in the human health risk assessment for children and adults, which was found not to reach a level of concern to the Agency (PP# 9F7528, DP Num.: 362855, W. Cutchin, 11/18/09).

Occupational Exposure

The previous occupational risk assessment considered exposure to workers from ground and aerial foliar applications of pyraclostrobin using more applications and at a higher total application rate than the proposed uses. Occupational pesticide handlers may experience short-and intermediate-term exposure to pyraclostrobin. The exposure for mixer/loaders workers was determined as the worst-case scenario. Dermal exposure risks were determined to not be of concern to the Agency provided mixer/loaders use protective gloves as specified on the product label. Inhalation exposure risks were also determined to not be of concern to the Agency if mixer/loaders support approximately 600 acres treated per day or if they use a dust/mist filtering respirator while supporting aerial applications of 1200 A treated/day. It is also possible for agricultural workers to have post-application exposure to pesticide residues during the course of typical agricultural activities. The most conservative estimate (i.e., highest exposure/risk) of post-application exposure resulted in exposure risks that did not exceed the Agency's level of concern (DP Num: 366927, M. Dow, 7/23/09).

Since the previous occupational risk assessment was conducted with a total application rate higher than the proposed uses on soybeans and exposure risks did not exceed the Agency's level of concern, the occupational risk from the proposed uses will also not exceed the Agency's level of concern.

Recommendation

There are no human health considerations that would preclude granting the requested uses of pyraclostrobin on soybean. ARIA recommends for increases in the following tolerances:

Soybean,	forage	. 11	ppm
Soybean,	hay	.14	ppm

Note to PM: It is recommended that the tolerance expression for 40 CFR § 180.474(a)(1) be changed to: "Tolerances are established for residues of the fungicide pyraclostrobin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate), calculated as the stoichiometric equivalent of pyraclostrobin, in or on the commodity."